NATIONAL CONSUMERS LEAGUE

1701 K Street, NW, Suite 1200, Washington, DC 20006

PHONE (202) 835-3323 FAX (202) 835-0747 www.nclnet.org

July 19, 2005

BY ELECTRONIC MAIL
http://www.fda.gov/dockets/ecomments

Division of Dockets Management (HFA –305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

COMMENTS OF THE NATIONAL CONSUMERS LEAGUE TO
DKT. No. 2005D–0169
DRAFT GUIDANCE ON USEFUL WRITTEN CONSUMER MEDICATION INFORMATION

The National Consumers League (NCL) is a private, nonprofit advocacy group representing consumers on marketplace and workplace issues. We are the nation's oldest consumer organization. NCL provides government, businesses, and other organizations with the consumer's perspective on concerns including child labor, privacy, food safety, and healthcare, including medication information. Our mission is to protect and promote social and economic justice for consumers and workers in the United States and abroad.

NCL has long been involved in issues of healthcare and monitors rulemakings and legislation involving health issues, provides and participates in patient education on medication and disease awareness, and researches factors that influence the provision of medical services to patients.

NCL has worked extensively and specifically in the issues surrounding communication of information to consumers about the drugs they take. Our research, educational activities, and advocacy have included:

- Reporting upon best practices in pharmacies to protect consumer privacy;
- Consumer education on pain relievers and on aspirin therapy
- Instruction on how to read an over-the-counter drug label;
- Awareness campaign for Attention Deficit/Hyperactivity Disorder;

- Testimony regarding COX-2 inhibitors;
- Testimony regarding methamphetamine manufacture;
- Publication of a Consumer Guide To Generic Drugs and a Cholesterol Fact Sheet;
- Instruction on how consumers can avoid counterfeit drugs
- Managing SOS Rx, a coalition on safe use of drugs in the outpatient setting; and
- Information to consumers on food – drug interactions.

Furthermore, NCL is a member of the Board of Directors of the National Council on Patient Education and Information (NCPIE), a coalition of over 125 organizations whose mission is to stimulate and improve communication of information on appropriate medicine use to consumers and healthcare professionals. NCPIE is the leading stakeholder coalition seeking to implement the Consumer Medicine Information (CMI) goals of Public Law No. 104-180. NCL was one of the participants on the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information – the Committee that ultimately submitted to The Honorable Donna E. Shalala an "Action Plan" (or "Keystone Report") for meeting the Public Law's targets for dissemination of useful CMI to patients.

NCL is pleased to submit comments to the Food and Drug Administration (FDA) on the draft guidance, "Useful Written Consumer Medication Information," 70 Fed. Reg. 30467 (May 26, 2005) (the Draft Guidance). We commend FDA for undertaking this effort to define for publishers and pharmacies what, in the agency's view, will be deemed "useful" CMI. However, NCL has some concerns with regard to the Draft Guidance and questions the extent to which the CMI the Draft Guidance contemplates will be useful to consumers.

1. CMI Derived From the Draft Guidance Will Often Be Too Long To Be Useful

Of particular concern to NCL is FDA's interpretation of the Action Plan to require that for CMI to be useful, it must include all indications, all contraindications, all warnings, and all precautions from the prescribed drug's FDA-approved package insert (PI) (also known as the full product labeling). FDA is, thus, essentially requiring the same information as is currently required for the brief summary that must accompany most prescription drug print advertising. *See* 21 C.F.R. § 202.1(e)(1). The Draft Guidance goes further even than FDA's brief summary regulations, requiring for instance, information on route of administration, monitoring of therapy, and other details. Consequently, for many prescription drugs, the CMI is going to become a very, very long document.

Yet, it has long been well known and documented that the typical brief summary – on which the CMI FDA contemplates in the Draft Guidance is based – is not meaningful for consumers. Indeed, FDA stated that a brief summary that repeats all of the risk information from the PI is:

> less than optimal for consumer-directed print advertisements because many consumers do not have the technical background to understand this information. Moreover, the volume of the material, coupled with the format in which it is presented (i.e., very small print and sophisticated medical terminology) discourages its use and makes the information less comprehensible to consumers. In general, FDA believes that exhaustive lists of minor risks distract from and make it difficult to comprehend and retain information on the more important risks. FDA also believes that information intended for a consumer should optimally be communicated in language fully understandable by a lay reader and presented in an easily readable format.

Draft Guidance: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements, 69 Fed Reg. 6908 (Feb. 10, 2004) (lines 66-72).

While the Draft Guidance would improve the formatting shortcomings of the usual small type brief summary, it does nothing to solve the comprehension and verbiage challenges of translating the risk information from the PI into a consumer-friendly document. The Draft Guidance does not resolve the significant problem of requiring inclusion of too much meaningless information that consumers do not read. Length is an important component of usefulness that FDA has not considered in the Draft Guidance. If important risk information is buried in a 4 page CMI, consumers will likely miss it. The experience of the brief summary dramatically illustrates that "more" is not "better" and certainly not "useful." Injury may result to consumers who are too intimidated to read a very lengthy CMI.

NCL believes, in the alternative, that the Draft Guidance should provide for CMIs that include a concise summary of the drug's important risk information, most common side effects, useage and storage instructions. In 2000, FDA proposed amending its regulations on the format and content of FDA-approved professional labeling for human prescription drug and biological products.[1] Under the proposed rule, FDA-approved professional labeling would contain a new introductory section called "Highlights of Prescribing Information" (Highlights). Highlights would set forth in a concise manner the information that is most important to safe and effective use of the drug, including information on the most common and the most serious risks associated with the product. NCL believes this Highlights concept is a better template for development of useful CMI.

2. The Draft Guidance Will Be Very Difficult To Implement

In addition, we fear that FDA has set up the conditions to make it very difficult for stakeholders to meet the 2006 goals of Public Law 104-180. The format and content

[1] Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirement for Prescription Drug Product Labels, 65 Fed. Reg. 81082 (Dec. 22, 2000).

changes presented in the Draft Guidance pose enormous implementation obstacles. Based upon the information presented during the NCPIE meetings (in which FDA has participated), altering the length and formatting of CMI will require massive changes to pharmacy computer printing systems that NCL doubts can be implemented in 2005. This means that FDA has posed minimum standards for compliant CMI, but not provided pharmacies, vendors, and CMI publishers sufficient time to meet the 2006 goals.

3. The Final Guidance Should Include The Sample Formats From The Action Plan

NCL is glad to see the Draft Guidance specify formatting requirements to assure that the CMI is readable and legible. However, we note that the Action Plan included specific sample examples in Appendix G. We recommend that FDA look to these samples in the final guidance as examples of CMI format that complies with the Action Plan.

* * *

NCL thanks FDA for this opportunity to comment.

Sincerely,

LINDA F. GOLODNER
President